

REMARKS

Reconsideration of this application in view of the above amendment and following remarks is respectfully requested.

Claims 1-19 are currently pending. Claims 20-47 have been withdrawn by the Examiner in response to Applicants' prior response to Restriction Requirement, and are canceled by way of this Amendment. Claim 1 has been amended merely for purpose of clarity for the reasons set forth below.

As an initial matter, Applicants note that all pending claims stand free of the art, and that the only outstanding issue has to do with clarity of the claims. More specifically, claims 1-19 stand rejected under the second paragraph of §112 as indefinite with regard to the meaning of the phrases "binding interaction parameter" and "mathematical expression" of claim 1. Applicants traverse these rejections for the following reasons.

As for the phrase "binding interaction parameter," Applicants submit that this phrase is readily understood by one skilled in this field. In addition, this same phrase is specifically defined in the specification at page 10, lines 14-18, as referring "to those constant or variable terms that are related to the binding interaction between a drug candidate and a sensing surface bound biomolecule." Such parameters include, for example, association and dissociation rate constants, as well as maximum binding capacity (*see* page 10, lines 18-19).

In view of this definition, Applicants submit that the rejected phrase is sufficiently clear to satisfy the second paragraph requirements of §112. However, for even further clarity, Applicants have amended claim 1 to recite, after the phrase "at least one binding interaction parameter of the drug candidate," the following additional text: "related to the binding interaction between the drug candidate and one or more sensing surface biomolecules." Such clarifying language is fully supported by the specification as originally filed, and does not constitute addition of new matter.

With regard to the phrase "mathematical expression", Applicants again submit that this phrase is sufficiently definite to satisfy the second paragraph requirements of §112. For example, as disclosed in the specification at page 22, lines 12-15, such a mathematical expression may be, for example, "a predetermined drug correlation graph to estimate one or

more absorption, distribution, metabolism and excretion [ADME] parameters of the drug candidate.” Representative drug correlation graphs are illustrated in Figures 5 and 7.

More specifically, in Figure 5 the binding interaction parameter (*i.e.*, binding levels at 100 μ M divided by the known drug compound’s molecular weight) is plotted along the *x*-axis, with the pharmacokinetic parameter (*i.e.*, distribution – percentage human serum albumin binding as determined by equilibrium dialysis) plotted along the *y*-axis. In Figure 7, the measured steady state binding levels (*i.e.*, a binding interaction parameter) for a number of different drugs is plotted against known data for the fraction absorbed (FA%) for humans (a pharmacokinetic parameter – absorption).

However, for purpose of clarity only, Applicants have amended claim 1 to recite at least one mathematical expression “correlating” (as opposed to “correlated from”) binding interaction data “measured for known drug compounds and known pharmacokinetic data” for the drug compounds to determine an estimate of the at least one pharmacokinetic parameter of the drug candidate. Again, such clarifying language is fully supported by the specification as originally filed, and does not constitute addition of new matter.

In view of the above remarks and clarifying amendments to claim 1, Applicants respectfully request that claim 1 (as well as claims 2-19 which depend therefrom) satisfy the second paragraph requirements of §112, and request that this ground of rejection be withdrawn. Alternatively, if Applicants have misunderstood the Examiner’s comments, the Examiner is respectfully requested to set forth in further detail his concerns with the pending claims such that Applicants can more fully address the same.

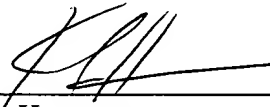
In view of the above remarks, allowance of claims 1-19 is respectfully requested. A good faith effort has been made to place this application in condition for allowance. However,

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should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at (206) 622-4900 to resolve the same.

Respectfully submitted,

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